

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIAL - PORTELA & CA S.A., BIAL -)
HOLDING, S.A., and SUNOVION)
PHARMACEUTICALS INC.,)
)
Plaintiffs,)
)
v.)
)
ALKEM LABORATORIES LIMITED) C.A. No. 18-304-CFC-CJB
)
Defendant.)
)
)

BIAL - PORTELA & CA S.A., BIAL -)
HOLDING, S.A., and SUNOVION)
PHARMACEUTICALS INC.,)
)
Plaintiffs,)
)
v.)
)
ALKEM LABORATORIES LIMITED) C.A. No. 20-786-CFC-CJB
)
Defendant.)
)
)

BIAL - PORTELA & CA S.A., BIAL -)
HOLDING, S.A., and SUNOVION)
PHARMACEUTICALS INC.,)
)
Plaintiffs,)
)
)
v.)
)
)
ALKEM LABORATORIES LIMITED) C.A. No. 21-186-CFC
)
)
Defendant.)
)
)

[PROPOSED] FINAL JUDGMENT

Whereas, Defendant Alkem Laboratories Limited has filed Abbreviated New Drug Application No. 211199 (“ANDA No. 211199”) seeking approval from the U.S. Food and Drug Administration to engage in the commercial manufacture, use, and/or sale of 200 mg, 400 mg, 600 mg, and 800 mg eslicarbazepine acetate tablets (“Alkem’s generic APTIOM® product”) before the expiration of Plaintiffs’ patents;

Whereas, on February 22, 2018, Plaintiffs filed a Complaint alleging that Alkem's filing of ANDA No. 211199 infringed U.S. Patent No. 8,372,431 ("the '431 patent") (Count I), U.S. Patent No. 9,206,135 ("the '135 patent") (Count II), U.S. Patent No. 9,566,244 ("the '244 patent") (Count III), U.S. Patent No. 9,643,929 ("the '929 patent") (Count IV), U.S. Patent No. 9,750,747 ("the '747 patent") (Count V), and U.S. Patent No. 9,763,954 ("the '954 patent") (Count VI) (C.A. No. 18-304-CFC-CJB, D.I. 1);

Whereas, on June 9, 2020, Plaintiffs filed a Complaint alleging that Alkem's filing of ANDA No. 211199 infringed U.S. Patent No. 10,675,287 ("the '287 patent") (C.A. No. 20-786-CFC-CJB, D.I. 1);

Whereas, on July 7, 2020, Plaintiffs filed an Amended Complaint in C.A. No. 20-786-CFC-CJB, alleging that Alkem's filing of ANDA No. 211199 additionally infringed U.S. Patent No. 10,695,354 ("the '354 patent") and U.S. Patent No. 10,702,536 ("the '536 patent") (D.I. 6);

Whereas, on February 10, 2021, Plaintiffs filed a Complaint alleging that Alkem's filing of ANDA No. 211199 infringed U.S. Patent No. 10,912,781 ("the '781 patent") (C.A. No. 21-186-CFC, D.I. 1);

Whereas, from February 2, 2018 until April 15, 2022, Plaintiffs asserted claims of the '431 patent, the '135 patent, the '244 patent, the '929 patent, and the '747 patent against Alkem;

Whereas, on April 15, 2022, Plaintiffs notified Alkem that they were no longer asserting any claims of the '135 patent or the '244 patent against Alkem;

Whereas, Plaintiffs continued to assert claims of the '431 patent, the '929 patent, and the '747 patent against Alkem until May 19, 2022, when, in response to the Court's Oral Orders of May 13, 2022 and May 16, 2022, Plaintiffs notified the Court and Alkem that they were no longer asserting any claims of the '431 patent,

the '929 patent, or the '747 patent against Alkem (C.A. No. 20-786-CFC-CJB, D.I. 231);

Whereas, on June 6, 2022, Alkem stipulated to a finding that its submission of ANDA No. 211199 for its generic APTIOM® product infringes claim 3 of the '287 patent, claim 5 of the '354 patent, and claims 7 and 8 of the '536 patent (C.A. No. 18-304-CFC-CJB, D.I. 241);

Whereas, the Court held a trial in the above-captioned cases from June 6, 2022 to June 8, 2022; and

Whereas, on September 15, 2022, the Court issued its Trial Opinion (C.A. No. 18-304-CFC-CJB, D.I. 271) concluding that (1) claim 3 of the '287 patent, claim 5 of the '354 patent, and claims 7 and 8 of the '536 patent are not invalid; (2) claim 17 of the '781 patent is invalid; and (3) through submission of ANDA No. 211199 to the FDA, Alkem has infringed and, if manufactured, used, offered for sale, or sold within the U.S. or imported herein, Alkem's generic APTIOM® product would infringe, claim 17 of the '781 patent if it were not invalid; and (4) claim 20 of the '954 patent is not infringed by inducement and is invalid; now therefore,

IT IS HEREBY ORDERED AND ADJUDGED THAT:

1. Final judgment is entered in favor of Plaintiffs and against Alkem that by submitting ANDA No. 211199 to the FDA, Alkem has infringed and, if manufactured, used, offered for sale, or sold within the U.S. or imported herein,

Alkem's generic APTIOM® product would infringe, claim 3 of the '287 patent, claim 5 of the '354 patent, and claims 7 and 8 of the '536 patent.

2. Final judgment is entered in favor of Plaintiffs and against Alkem that claim 3 of the '287 patent, claim 5 of the '354 patent, and claims 7 and 8 of the '536 patent are not invalid for the reasons set forth in the Court's Trial Opinion.

3. Final judgment is entered in favor of Alkem and against Plaintiffs that claim 17 of the '781 patent is invalid for the reasons set forth in the Court's Trial Opinion.

4. Final judgment is entered in favor of Plaintiffs and against Alkem that by submitting ANDA No. 211199 to the FDA, Alkem has infringed and, if manufactured, used, offered for sale, or sold within the U.S. or imported herein, Alkem's generic APTIOM® product would infringe, claim 17 of the '781 patent if it were not invalid.

5. Final judgment is entered in favor of Alkem and against Plaintiffs that claim 20 of the '954 patent is not infringed by inducement and is invalid for the reasons set forth in the Court's Trial Opinion.

6. Alkem shall notify the FDA in writing within 5 days after entry of this final judgment (with a copy of such notice given simultaneously to Plaintiffs) of the Trial Opinion that claim 3 of the '287 patent, claim 5 of the '354 patent, and claims 7 and 8 of the '536 patent are valid and that Alkem's filing of ANDA No. 211199

infringes claim 3 of the '287 patent, claim 5 of the '354 patent, and claims 7 and 8 of the '536 patent, as set forth above in paragraphs 1 and 2.

7. Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any final approval by the FDA of Alkem's generic APTIOM® product shall be a date that is not earlier than the date of expiration of each of the '287, '354, and '536 patents, and any extensions thereof, currently May 6, 2025.

8. Pursuant to 35 U.S.C. § 271(e)(4)(B), Alkem and each of its officers, agents, servants, employees, successors, and attorneys, and all persons and entities acting in concert or participation with them, are enjoined, until the expiration of each of the '287, '354, and '536 patents, from commercially manufacturing, using, selling or offering for sale in the United States, or importing into the United States, Alkem's generic APTIOM® product.

9. Counts I through V of Plaintiffs' Complaint filed in C.A. No. 18-304-CFC-CJB (D.I. 1), as well as any related counterclaims filed by Alkem (*see* D.I. 13), are dismissed with prejudice.



CLF

CHIEF JUDGE

Dated: 10-24-22